Draft June 2011

Stratton VA Medical Center
IRB Standard Operating Procedure:
Exempt Review of Research

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local guidelines in the conduct of clinical research studies. Written procedures are required to guide the IRB in the exempt review of research.

REFERENCES

45 CFR 46

38 CFR 16

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

PROCEDURE

All research meeting the DHHS or FDA definition of human subject research must be reviewed by the IRB. For studies in which exemption is being requested, **the Institutional Review Board (IRB) chair, vice chair or designee must approve the exempt status.**

The application and accompanying documents the investigator submits provide information that enables the IRB Chair or designee to determine if exemption meets the required criteria. The prospective investigator will submit the Stratton VAMC IRB Form – Request for Exempt Protocol Approval – and accompanying documents to the HRPP Coordinator, who will then deliver these to the IRB Chair or designate within three business days of receipt.

The IRB Chair or designee will review the abstract of the proposed research to assure that the proposed research meets the exemption criteria as defined by 38 CFR 16 101 (b) (see below).

ISSUES AND IMPLEMENTATION OF 38 CFR 16.101(b)

Research activities in which the only involvement of human subjects will be in one or more of the minimal risk categories listed below are exempt from the requirements of the Common Rule

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This exemption does not apply if the setting is not commonly recognized as an educational one, or if other than normal educational practices are employed. Even if the research is exempt, the investigator has an ethical obligation to ensure that students' rights and welfare are respected. When educational institutions become engaged in the actual conduct of research, they are required to file an Assurance in accordance with VA regulations at 38CFR16.103(a). This exemption does not apply if the research involves prisoners or is FDA-regulated.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation ***or (VHA 1200.05) place the subject at risk for loss of insurability****. This exemption does not apply if the research involves prisoners or is FDA-regulated. This exemption does not apply to research involving children when the research includes observation of public behavior where the investigator participates in the activities being observer, survey procedures, or interview procedures.*

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s)without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. This exemption does not apply if the research involves prisoners or is FDA-regulated.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This exemption does not apply if the research involves prisoners or is FDA-regulated.

NOTE: The information must exist at the time the research is proposed and initiated.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv)possible changes in methods or levels of payment for benefits or services under those programs. Research in this category must: a) Be conducted pursuant to federal statutory authority, b) Have no statutory requirements for IRB review, c) Not involve significant physical invasions or intrusions upon the privacy interests of participants, AND d) Have authorization or concurrence by the funding agency. This exemption does not apply if the research involves prisoners or is FDA-regulated.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. This exemption does not apply if the research involves prisoners (*See Determining Whether a Proposed Activity is Research Involving Human Subjects According to FDA or DHHS Regulatory Definitions).*

Investigator Procedures

Investigators wishing to have a research protocol or protocol change exempted from IRB review must present the request in writing, along with the research proposal and required forms, to the IRB Chair or designee. The investigator must indicate the specific criterion, from those listed above {38CFR16.101 (b)(1-6)}, believed to be appropriate for exempting the proposal. The investigator is to follow the procedures applicable to the type of item submitted (i.e., if a new proposal, all required forms must be submitted). Once approved, it is the Investigator's responsibility to assure that the research project continues to meet the criteria for exemption from IRB review.

R&D Office Administrative Procedures

Upon receipt of a request for exemption, R&D Office staff will check for completeness and assign the review to the IRB chair, vice chair or an IRB member designated by the IRB chair or vice chair. Documentation of verified exemptions, inclusive of the basis for the exemption according to federal regulations, will be documented in the minutes of the IRB. VA Policy does not permit a research project to begin until the R&D Committee's approval is obtained.

Once approved, the ACOS/R will generate a letter of approval which will include the category of the exemption. This letter is forwarded to the Principal Investigator. If it is determined that the project does not qualify for exemption, the principal investigator is also notified.

Approved exempt protocols do not require continuing review by the IRB or R&D Committees. However, the PI is responsible for notifying the R&D committee, via the R&D program office / R&D Committee coordinator, of study closure, using the standard study closure forms.

Reviewer Procedures

Upon referral of an exemption request from the R&D Office, the IRB member will fully review the request, including the protocol, verify that it meets one of the criteria listed above, approve or deny the exemption, and sign the determination.

The documentation will include the specific categories justifying the exemption or, if the request is denied, include the reason for the denial.

Along with reviewing the protocol exemption request, the IRB member reviewer must assure that the protocol meets the ethical standards of Stratton VAMC. This assurance will be determined by reviewing the protocol to assure the following considerations are addressed:

- The research holds out no more than minimal risk to participants.
- Selection of participants is equitable and the privacy interests are addressed
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose such information as the following – it should be noted that such a determination will be tantamount to determining that the study does meet the criteria for exemption:
  - That the activity involves research.
  - A description of the procedures.
  - That participation is voluntary.
  - Name and contact information for the researcher.